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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,902 | 07/02/2002 | Nikolai Vladimirovich Bovin | 9286-7 | 7167 |

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| EXAMINER | |
|---|---|
| FONDA, KATHLEEN KAHLER | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/019,902 | BOVIN ET AL. | |
| | Examiner | Art Unit | |
| | Kathleen Kahler Fonda, Ph.D. | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *7-2-02 (prel amdt)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12,14-16,18,20,23, and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12,14-16,18,20,23 and 25-29* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESTRICTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12, 14-16, 18, 20, 27, and 28, drawn to a compound wherein at least one R must be a ligand suitable for specific bonding to a receptor, a marker molecule, or a catalytically active group; aggregates thereof; a method of changing the structure of the aggregate; a method of preparing a drug comprising the compound; and a method of treating disease by administering the compound.

Group II, claims 23, 25, and 26, drawn to a compound which lacks any R moieties as in Group I and instead has hydrogen in their place(s); a method of preparing a drug comprising the compound; and a method of treating disease by administering the compound.

Group III, claim 29, drawn to a method of preparing a diagnostic test which comprises providing a test reagent, preparing a compound as described in Group I, and comparing the test reagent to the compound.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The compounds of Group I and Group III differ from those of Group II because the compounds of Group I and Group III require a ligand suitable for specific bonding to a receptor, a marker molecule, or a catalytically active group, while those of Group II do not. There is no recognition in the art that compounds of Group I and Group III on one hand

and compounds of Group II on the other would be expected to have the same utility. Thus Group II does not have a corresponding special technical feature with Groups I and III. Group III, while requiring the same compound as Group I, also requires a test reagent which is a distinct feature. Furthermore, Group I includes claims drawn to a method of treatment using the compound, and Group III recites a distinct method of preparing a diagnostic test which uses the same compound. Unity of invention is not recognized between more than one method of using the same compound; see Annex B, Part 1, section (e) of the Administrative Instructions Under the PCT, available beginning at the bottom of page AI-63 of the February 2003 edition, revision 1, of the MPEP. Thus Group I does not have a corresponding special technical feature with Group III.

ELECTION OF SPECIES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A mono- or oligosaccharides

Species B peptides

Species C mono- or oligonucleotides

Species D nucleic bases

Regardless of which of Groups I-III is elected, Applicant is further required, in reply to this action, to elect a single species from among Species A-D above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner. Claims 1-6, 9-12, 14-16, 18, 20, 23, and 25-29 are generic. Claims 7 and 8 are subgeneric. No claim is limited to a species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Neither the compounds of Groups I and III, nor the compounds of Group II, have a significant structural element which is shared by all of the alternatives. See Annex B, Part 1, section (f), entitled "Markush Practice," of the Administrative Instructions Under the PCT, available

beginning on page AI-64 of the February 2003 edition, revision 1, of the MPEP.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
Art Unit 1623